

Food and Drug Administration Kansas City District Southwest Region 11630 West 80<sup>th</sup> Street Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

September 25, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER Ref. KAN #2002-011

Thomas A. Kruse, President Iowa Veterinary Supply Company 124 Country Club Road Iowa Falls, IA 50126

Dear Mr. Kruse:

Recently an inspection was made of your veterinary drug sales facility located at 3000 Highway 75 North, Sioux City, Iowa. This inspection was conducted from June 11 to 17, 2002, by a Food and Drug Administration Investigator from this office who documented sales of prescription drugs for veterinary use that are adulterated within the meaning of Section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (Act) and misbranded within the meaning of Section 502(f)(1) of the Act

The drugs "Amoxicillin Oral Suspension USP" and "Sulfamethoxazole and Trimethoprim Oral Suspension USP" among others, are human drugs that are being dispensed for animal use without the required labeling, including adequate directions for use.

Under Section 512(a)(5), a drug approved for human use may be used in animals if its use is on the lawful order of a veterinarian and is in compliance with the regulations at 21 CFR Part 530. The human drugs you are dispensing for veterinary use are not in compliance with 21 CFR 530.12 because they do not bear the required labeling information

Because your products do not comply with the applicable regulations, they are unsafe within the meaning of Section 512(a) and are thus adulterated under Section 501(a)(5).

In addition, because your products are dispensed without adequate directions for use, they are misbranded under Section 502(f).

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence at any of the established locations within your company. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

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The violation listed above is not intended to be all-inclusive. You, as a corporate official of this firm, have a responsibility to insure that all drugs intended for veterinary use, which bear the human or veterinary prescription legend, are sold by you or your firm properly labeled as required.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

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Sincerely,

Charles W. Sedgwick

District Director

Kansas City District

Clarence D. Pippett
Manager
Iowa Veterinary Supply Co.
3000 Highway 75 North
Sioux City, IA 51105